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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO.       |
|--|-------------|----------------------|------------------------------|------------------------|
| 10/579,605   | 05/17/2006  | Shun-ichi Harada     | 21350YP                      | 9392                   |
| 210 7590 03/28/2008<br>MERCK AND CO., INC<br>P O BOX 2000<br>RAHWAY, NJ 07065-0907 |             |                      | EXAMINER<br>GAMETT, DANIEL C |                        |
|  |             |                      | ART UNIT<br>1647             | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>03/28/2008      | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/579,605

**Applicant(s)**

HARADA ET AL.

**Examiner**

DANIEL C. GAMETT

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) 1, 3-9 and 11 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-16 is/are allowed.
- 6) ☒ Claim(s) 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 04/20/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election without traverse of claims 10 and 12-16 in the reply filed on 01/17/2008 is acknowledged.
2. Claims 1, 3-9, and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/17/2008.
3. Claims 10 and 12-16 are under consideration.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 7057017, filed March 5, 1999. Claim 12 is drawn to an isolated and purified rhesus dickkopf-1 (rhDkk-1) polypeptide comprising a sequence of amino acids as set forth in SEQ ID NO:2. The limitation “a sequence of amino acids as set forth in SEQ ID NO:2” (as opposed to *the* sequence of amino acids as set forth in SEQ ID NO:2) is anticipated by any sequence, even as short as two consecutive amino acids, that is found in SEQ ID NO:2. The '017 patent teaches a dkk-related

polypeptide (SEQ ID NO:8) that is 98.5 % identical to SEQ ID NO:2. Thus, this prior art polypeptide comprises many sequences set forth in SEQ ID NO:2. These include, for example, the polypeptide comprising amino acids 85-138 of SEQ ID NO:8 recited in claim 5 of the '017 patent, which is 100% identical to the corresponding sequence in SEQ ID NO:2 (see alignment below; the query sequence is SEQ ID NO:2). Such sequences are indistinguishable from the instantly claimed sequences. The recitation of an origin, rhesus, indicates a process for isolation of the claimed product. The courts have established that if a claimed product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe.*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

Query Match 98.5%; Score 1438; DB 3; Length 266;  
Best Local Similarity 97.7%; Pred. No. 3.2e-131;  
Matches 260; Conservative 4; Mismatches 2; Indels 0; Gaps 0;

Qy 1 MMALGAAGAARVLVALVAAALGGHPLLGSATLNSVLNSNAIKNLPPPLGGAAGHPGSAV 60  
||| ||| |:: ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||  
Db 1 MMALGAAGATRVEFVMVAALGGHPLLGSATLNSVLNSNAIKNLPPPLGGAAGHPGSAV 60

Art Unit: 1647

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Qy      61  SAAPGILYPGGNKYQTIIDNYQPYPCAEDEECGTDEYCASPTRGGDAGVQICLACRKRKR120
         |
Db      61  SAAPGILYPGGNKYQTIIDNYQPYPCAEDEECGTDEYCASPTRGGDAGVQICLACRKRKR120
         |
Qy     121  CMRHAMCCPGNYCKNGICVSSDQNNFRGEIETITESFGNDHSTLDGYSRRTTLSSKMYH180
         |
Db     121  CMRHAMCCPGNYCKNGICVSSDQNNFRGEIETITESFGNDHSTLDGYSRRTTLSSKMYH180
         |
Qy     181  SKGQEGSVCLRSSDCATGLCCARHFWSKICKPVLKEGQVCTKRRRGSHGLEIFORCYCG240
         |
Db     181  SKGQEGSVCLRSSDCASGLCCARHFWSKICKPVLKEGQVCTKRRRGSHGLEIFORCYCG240
         |
Qy     241  EGLSCRIQKDDHQAASNSRLHTCQRH 266
         |
Db     241  EGLSCRIQKDDHQAASNSRLHTCQRH 266

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### *Conclusion*

7. Claim 10 is rejected.
8. Claims 12-16 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD., whose telephone number is (571)272-1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel C Gamett/  
 Examiner, Art Unit 1647  
 28 March 2008